

OCT 30 2003

K032002

510(k) SUMMARY

Name of 510(k) sponsor: Genosis Ltd..
Address: 12-50 Kingsgate Road
Kingston Upon Thames
England KT2 5AA

Telephone: (44) 208 408 5232
Fax: (44) 208 408 5432

Contact information: Paul Bateman
President & CEO
Genosis Ltd.

Telephone: (44) 208 408 5246
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Date summary prepared: June 27, 2003

Proprietary name of device: Fertell Female Fertility Test

Generic/classification name: Follicle Stimulating Hormone (FSH) Test, Over the Counter

Product code (classification): NGA (Follicle Stimulating Hormone (FSH) Test, Over the Counter)
21 C.F.R. § 862.1300

Legally Marketed Predicate Devices:

Instacheck Menopause Predictor Test (K023408)

Surestep FSH Menopause Test (K010556)

Genua Menopause Monitor Test Kit (K002450)

AxSYM Follicle Stimulating Hormone (K935612)

MAIAclone™ FSH Assay (K862813)

FIRST RESPONSE Ovulation Predictor Test (K953581)

Device Description and Technological Characteristics:

The Fertell Female Fertility Test is a dipstick, lateral flow rapid test that measures FSH in an in-stream urine sample. The test is performed two days after the onset of menses (day 3 of the menstrual cycle) and is similar in design and use to a pregnancy test or an ovulation prediction test. It uses a monoclonal antibody to one antigenic determinant that is conjugated with colloidal gold and a second monoclonal antibody to a different antigenic determinant, the latter antibody being immobilized as a line on a nitrocellulose strip. FSH present in the urine reacts with the conjugated antibody and immobilized antibody, forming a “sandwich” immunocomplex at the site of the immobilized antibody. Unreacted conjugate is washed from the strip by the flow of excess sample. The appearance of a clear red line (test result) indicates FSH in the urine sample, with the intensity of the line proportional to the FSH concentration.

The nitrocellulose strip also has a comparator line of fixed intensity that corresponds to an FSH concentration of 10 IU/L. A test line of color intensity greater than or equal to the comparator line indicates a concentration of FSH of 10 IU/L or greater. This level is indicative of diminished ovarian reserve.

Intended Use

The Fertell Female Fertility Test is intended to measure Follicle Stimulating Hormone ("FSH") in urine as an adjunctive screen of fertility for home use by women who are attempting to conceive but have been unsuccessful.

Testing

The consumer study demonstrated that the Fertell Female Fertility Test could be accurately performed by a general public consumer population in the home environment (correct response level >97%). The lay user also demonstrated >90% accuracy when compared to a professional, and when compared to a quantitative serum FSH tests, the Fertell Female Fertility test demonstrated >95% accuracy.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 30 2003

Genosis Ltd.
c/o Sharon A. Segal, Ph.D.
Director of Regulatory Science
Morgan, Lewis & Bockius
1111 Pennsylvania Avenue N.W.
Washington, D.C. 20004

Re: k032002
Trade/Device Name: Fertell Female Fertility Test
Regulation Number: 21 CFR 862.1300
Regulation Name: Follicle-stimulating hormone test system
Regulatory Class: Class I
Product Code: NGA
Dated: September 15, 2003
Received: September 15, 2003

Dear Dr. Segal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

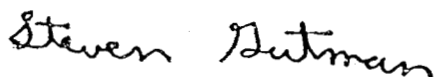
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant: Genosis Ltd.

510(k) Number: K032002

Device Name: Fertell Female Fertility Test

Indications for Use:

The Fertell Female Fertility Test is intended to measure Follicle Stimulating Hormone ("FSH") in urine as an adjunctive screen of fertility for home use by women who are attempting to conceive but have been unsuccessful.

Carol Benson for Jean Cooper, OVM
Division Sign-Off

**Office of In Vitro Diagnostic Device
Evaluation and Safety**

510(k) K032002

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

or

Over-the Counter Use ✓